

Applicants: Tilla S. Worgall and Richard J. Deckelbaum  
Serial No.: 10/712,684  
Filed: November 14, 2003  
Page 5

**REMARKS**

Claims 1, 5-16 and 44-49 are pending and under examination in the subject application.

Applicants have amended the abstract of the specification such that it complies with the proper format and language for an abstract.

The Examiner indicated in the June 5, 2007 Office Action that claims 11, 13-16, and 44-49 are withdrawn from consideration. Applicants herein cancel claims 1, 13-16 and 44-49 without disclaimer or prejudice to their right to pursue the subject matter of these claims in the future.

Applicants have also amended claim 1 to more particularly point out that which the applicant regards as the invention. Support for amended claim 1 can be found in the specification at, *inter alia*, paragraphs 68, 69 and 72.

Applicants maintain that this Amendment raises no issue of new matter. Accordingly, upon entry of the Amendment, claims 1, 5-10 and 12 will be pending and under examination in the subject application.

**Elections/Restrictions**

The Examiner addressed applicants' traversal of the restriction requirement set forth in the November 27, 2006 Office Action. Applicants acknowledge the Examiner's decision that the restriction requirement is proper and therefore made final.

Applicants: Tilla S. Worgall and Richard J. Deckelbaum  
Serial No.: 10/712,684  
Filed: November 14, 2003  
Page 6

**Objection to the Specification**

The Examiner objected to the specification because the abstract contains the word "comprising". The Examiner reminded applicant that the specification should be in narrative form, limited to a single paragraph within the range of 50-150 words, and should avoid the form and legal phraseology of patent claims.

In response, applicants note that the abstract has been amended herein to comply with the proper format and language for an abstract. Accordingly, applicants maintain that the objection to the specification has been overcome.

**Rejection under 35 U.S.C. §102(b)**

The Examiner rejected claims 1, 6, 8-10 and 12 under 35 U.S.C. §102(b) as allegedly anticipated by Riley, et al. ("Serine palmitoyltransferase inhibition reverses anti-proliferative effects of ceramide synthase inhibition in cultured renal cells and suppresses free sphingoid base accumulation in kidney of BALBc mice", Environmental Toxicology and Pharmacology, 7:109-118 (1999)).

Specifically, the Examiner indicated that Riley, et al. teaches the contacting of myriocin to cells and the administration of myriocin to mice. The Examiner further indicated that although Riley, et al. does not specifically state that administration of myriocin results in a decrease in mSREBP, a compound and its properties are inseparable. Therefore, the Examiner alleged that Riley, et al. reads upon the claimed invention.

In response, applicants note that claim 1, as amended, recites a

Applicants: Tilla S. Worgall and Richard J. Deckelbaum  
Serial No.: 10/712,684  
Filed: November 14, 2003  
Page 7

method for decreasing the amount of mature sterol regulatory element binding proteins and cholesterol synthesis in a human cell. Applicants note that all experiments disclosed in Riley, et al. were performed on non-human cells or subjects, and that nowhere does Riley, et al. teach a method directed to human cells. Furthermore, applicant notes that previously pending claim 5, which provided the method of claim 1 wherein the cell is a human cell, was not rejected as anticipated by Riley, et al. Accordingly, applicants maintain that amended claim 1, and dependent claims 6, 8-10 and 12, are not anticipated by Riley, et al.

Applicants respectfully request that the Examiner reconsider and withdraw the rejection under 35 U.S.C. §102(b).

**Rejection under 35 U.S.C. 103(a)**

The Examiner further rejected claims 1, 5-10 and 12 under 35 U.S.C. §103(a) as allegedly obvious by Riley, et al.

In support of the obviousness rejection, the Examiner reiterated the remarks made in support for the rejection under 35 U.S.C. §102(b). The Examiner further indicated that the one skilled in the art would understand that various cell types, including adipocytes, would be contacted by myriocin when myriocin is administered to an animal, as taught in Riley, et al. The Examiner further indicated that Riley, et al. alludes to the use of human trials.

In response, applicants note that claim 1, as amended, recites a method for decreasing the amount of mature sterol regulatory element binding proteins and cholesterol synthesis in a human cell characterized by an elevated level of mature sterol

regulatory element binding proteins comprising contacting the cell with an agent that specifically inhibits *de novo* synthesis of ceramide in the cell, so as to thereby decrease the amount of mature sterol regulatory element binding proteins and cholesterol synthesis in the cell.

Applicants assert that the subject invention is based on the new and nonobvious use for inhibitors of *de novo* synthesis of ceramide in a cell, and that the prior art actually taught away from the claimed invention. Specifically, applicants note that as disclosed in the subject application at paragraph 99, one skilled in the art would have expected that inhibition of *de novo* ceramide synthesis would increase the level of mature sterol regulatory element binding proteins in a cell. However, applicants unexpectedly discovered that inhibition of *de novo* ceramide synthesis decreased SRE-mediated gene transcription (See, for example, paragraph 99 of the subject application).

Applicants further maintain that Riley, et al. does not render obvious applicants' claimed invention. Specifically, Riley, et al. teach the use of inhibitors of *de novo* ceramide synthesis to reduce the deleterious effects of fumonisins in animals suspected or known to have consumed toxic levels of fumonisins in feeds. Nowhere does Riley, et al. suggest the use of inhibitors of *de novo* ceramide synthesis for decreasing the amount of mature sterol regulatory element binding proteins and cholesterol synthesis in a human cell. Applicants assert that the claimed method of the subject application would not have been obvious based on the disclosure of Riley, et al.

Applicants further maintain that Riley, et al. teach away from the claimed invention. Specifically, the claimed invention

encompasses the use of either myriocin, a serine palmitoyltransferase inhibitor, or Fumonisin B1, a ceramide synthase inhibitor, to decrease the amount of mature sterol regulatory element binding proteins and cholesterol synthesis in a human cell. In contrast, Riley, et al. disclose the use of myriocin to inhibit the deleterious effects of fumonisins in animals. Riley, et al. do not render obvious either the use of Fumonisin B1 (or any ceramide synthase inhibitor) or myriocin (or any serine palmitoyltransferase inhibitor) to decrease the amount of mature sterol regulatory element binding proteins and cholesterol synthesis in a human cell.

In summary, Riley, et al. merely teach that myriocin, a serine palmitoyltransferase inhibitor, can be used to reduce the harmful effects of fumonisins in animals. Riley, et al. do not render obvious the use of inhibitors of *de novo* ceramide synthesis to decrease the amount of mature sterol regulatory element binding proteins and cholesterol synthesis in a human cell.

In view of the preceding, applicants respectfully request that the Examiner reconsider and withdraw the rejection under 35 U.S.C. §103(a).

#### **Summary**

In view of the amendments to claim 1 and the preceding remarks, applicants maintain that the pending claims are in condition for allowance.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

Applicants: Tilla S. Worgall and Richard J. Deckelbaum  
Serial No.: 10/712,684  
Filed: November 14, 2003  
Page 10

No fee is deemed necessary in connection with the filing of this Amendment. However, if any fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

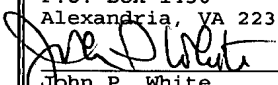
Respectfully submitted,



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